



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

99349-1

Date of Issuance:

3/14/22

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

HY-GEN

Name and Address of Registrant (include ZIP Code):

Brian Hogan
Saltwater Biocides, Inc.
12607 NE 95th St. #A100
Vancouver, WA 98682

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Signature of Approving Official:

Demson Fuller Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

3/14/22

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 99349-1."
4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 08/06/2021

If you have any questions, please contact Melanie Bolden by phone at (202) 566-0674, or via email at Bolden.Melanie@epa.gov

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Throughout the label, { } indicates Notes to the Reviewer, [] indicates optional text and () indicates clarifications and acronyms.

SALTWATER BIOCIDES, INC.

HY-GEN

[Alternative Brand Names: HYGEN, HYGEN-200, Hy-Gen 200, HYGEN-500, HY-Gen 500]

Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

HY-GEN

- A hospital disinfectant
- Produced for use in Medical, Dental, Hospitality, Industrial, Residential, Veterinarian and Commercial applications
- Produced with low costs from salt, water and electricity

ACTIVE INGREDIENT

Hypochlorous Acid.....0.029%

OTHER INGREDIENTS.....99.971%

TOTAL.....100.000%

Contains 500 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

EPA Registration Number 99349-1

EPA Establishment Number 99349-1-WA

MANUFACTURED BY:
Saltwater Biocides, Inc
Vancouver, WA 98682
www.saltwaterbio.com
12607 NE 95th St. #A100
360-718-3488

Date Produced_____

HY GEN must be used within 14 days after production OR tested with chlorine strip. DO NOT USE PRODUCT when Chlorine concentration is below 450 ppm FAC.

NET CONTENTS: X [FL OZ] [PT.] [QT.] [GAL.] [mL] [L]

ACCEPTED

03/14/2022

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 99349-1

HY-GEN Disinfectant is a Hypochlorous Acid solution produced by passing an aqueous saline solution (brine) through 1 or more electrolytic cells. The current within the electrolytic cell(s) converts the sodium chloride compound into Hypochlorous Acid, an oxidizing agent exhibiting antimicrobial properties.

HY-GEN properties are closely controlled by controlling the voltage and the current to the electrolytic cell(s), brine conductivity, temperature and flow rate through the cells as well the pH of the Hypochlorous Acid generated in the cell(s).

HY-GEN freezes at 32 degrees Fahrenheit and boils at 212 degrees Fahrenheit. It is a colorless and aqueous solution with a slight chlorine odor.

PRECAUTIONARY STATEMENTS:

Physical and Chemical Hazards: HY-GEN is not compatible with other chemicals such as acids and hydrogen peroxide.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Hard, Non-Porous Surface Disinfection

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For visibly soiled areas, a preliminary cleaning is required. Spray HY-GEN on hard, non-porous surfaces. Treated surfaces must remain visibly wet for 5 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that, (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

ORGANISM TABLE FOR DISINFECTING APPLICATIONS

Bacteria: Broad Spectrum & Hospital	Contact Time
Staphylococcus aureus (ATCC 6538)	5 Min
Pseudomonas aeruginosa (ATCC 15442)	5 Min
Salmonella enterica (ATCC 10708)	5 Min
Viruses	
Rhinovirus Type 37 (ATCC VR-1147, Strain 151-1)	5 Min

EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This Product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped Virus	Rhinovirus Type 37
Large, non-enveloped virus	Rhinovirus Type 37

HY-GEN has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, HY-GEN can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. HY-GEN kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

CLAIMS

- This product was tested according to AOAC methods
- Meets surface disinfection recommendations from OSHA Bloodborne Pathogen Standard
- Broad spectrum disinfectant
- One step cleaner/disinfectant when used according to the disinfection directions
- Cleaner/disinfectant
- Hypochlorous Acid [(HOCl)] Solution
- Hospital Disinfectant
- Active ingredient hypochlorous acid [(HOCl)] produced from water and salt
- [Antimicrobial] [bactericidal] [disinfectant]
- Aids in the reduction of cross-contamination between treated surfaces
- [Bactericide] [Bactericidal]
- [Virucide*] [Virucidal*]
- [Germicide†] [Germicidal†]
- Bathroom disinfectant on hard, non-porous surfaces
- Kitchen disinfectant on hard, non-porous surfaces
- Nursery disinfectant on hard, non-porous surfaces
- Athletic facility disinfectant on hard, non-porous surfaces
- Can be sprayed
- Cleans and disinfects {insert use site} when used according to disinfection directions
- Cleans and disinfects hard, non-porous surfaces when used according to disinfection directions

- Cleans, deodorizes and disinfects when used according to disinfection directions
- Deodorizes by killing the bacteria that causes odors
- Designed for practical use
- Designed to save you time
- Disinfecting formula
- Disinfects and deodorizes by killing bacteria and their odors
- Disinfects hard, non-porous surfaces [throughout the {insert use site}]
- Convenient disinfecting
- One-step cleaning and disinfecting when used according to disinfection directions
- [Effective against] [Kills] {insert any organism(s) from table above} [in the presence of 5% organic soil load]
- Effective against Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica
- Eliminates odors at their source; [bacteria]
- [Eliminates] [Removes] [smoke] [urine] [feces] [fish] [foul] [body] odors
- [Eliminates] [Removes] pet odors like [urine] [feces] [vomit] [“wet dog”] [smell]
- [Eliminates] [Reduces] odors caused by [bacteria] [in the kitchen] [in the bathroom]
- [Eliminates] [removes] Odors
- For daily use
- For use {insert one or more of the use sites listed on the label}
- For use on {insert one or more of the use surfaces listed on the label}
- For use on high touch surfaces
- [Kills] [Eliminates] 99.9% [Effective against] [of] Staphylococcus aureus on hard, non-porous surfaces
- [Kills] [Eliminates] 99.9% [Effective against] [of] Pseudomonas aeruginosa on hard, non-porous surfaces
- [Kills] [Eliminates] 99.9% [Effective against] [of] Salmonella enterica on hard, non-porous surfaces
- Can help reduce the risk of cross contamination between treated hard, non-porous surfaces
- 2 in 1 Formula [Cleaner and odor eliminator]
- Inspired by how you want [need] to disinfect
- Invented to disinfect the way you [want] [need]
- Kills bacteria
- Kills odor-causing bacteria
- Kills bacteria [and] [rhinovirus]
- Kills [bacteria] [and] [rhinovirus] [on hard non-porous surfaces] [you touch most]
- Low Odor
- [Fresh] [Clean] Scent
- The smell of clean
- Breathe Easy: [Fragrance Free] [No Harsh Fumes]
- Worry free use in [kennels] [litter box] [pet areas] [baby rooms] [nurseries]
- Use for a [fresh] [home] [environment] [kitchen]
- Alcohol free [formula]
- Dye free [formula]
- Fragrance free [formula] [will not irritate your [dog’s] [pet’s] nose]
- Phenol free [formula]
- VOC free [formula]

- [No] [Never] any [alcohol] [dyes] [fragrances] [phenols] [VOCs] [harsh fumes]
- Non-flammable [formula] [Kills] [Effective against] pathogen[†]
- Made in the USA {may include graphic of American flag}
- One-step cleaner and disinfectant when used according to disinfection directions
- Cleans and disinfects hard, non-porous environmental surfaces in [health care facilities] [or] [{insert use site}] when used according to disinfection directions
- Ready-to-use [cruise line] [daycare] [dental] [hospital] [household] [institutional] [residential] [veterinarian] disinfectant
- Ready-to-Use [Formula]
- No mixing required
- Disinfectant to go
- The answer to your disinfecting needs
- The convenient way to disinfect
- Use in [public] [common] places where [bacteria] [and] [rhinovirus] may be of concern on hard, non-porous surfaces
- Non-greasy [formula]
- Non-sticky [formula]
- Leaves no [sticky] [greasy] [flammable] [harmful] residue on surfaces [after evaporation]
- Contains no phosphates
- [Kills] [Effective against] bacteria
- [Kills] [Effective against] rhinovirus
- Consumer Disinfectant on hard, non-porous surfaces
- Commercial Disinfectant on hard, non-porous surfaces
- Cruise Line Disinfectant on hard, non-porous surfaces
- Dental Disinfectant on hard, non-porous surfaces
- Freight Disinfectant on hard, non-porous surfaces
- Hospital Disinfectant on hard, non-porous surfaces
- Hospitality Disinfectant on hard, non-porous surfaces
- Industrial Disinfectant on hard, non-porous surfaces
- [Janitorial] [Jan-San] Disinfectant on hard, non-porous surfaces
- Nursery Disinfectant on hard, non-porous surfaces
- Public Transportation Disinfectant on hard, non-porous surfaces
- Residential Disinfectant on hard, non-porous surfaces
- Retail Disinfectant on hard, non-porous surfaces
- Veterinarian Disinfectant on hard, non-porous surfaces
- [Sample] [travel] size

CLAIM QUALIFIERS

{Note to Reviewer: If claims with a qualifier are used, the applicable qualifier(s) below must also appear on the label}

* Rhinovirus Type 37

† Staphylococcus aureus, Pseudomonas aeruginosa, Rhinovirus Type 37

GENERAL CLAIMS

- Convenient
- For General Use
- Easy to Handle
- For use on Bathroom Surfaces
- For use in Athletic Facilities
- For use on Athletic Equipment
- For use on Nursery Surfaces
- Suitable for hospital use
- Will not Harm Hard, Non-Porous Inanimate Environmental Surfaces
- Will not Harm Titanium-Coated, Medical Grade Stainless Steel

USE SURFACES

- Ceramic Glazed Tile
- Chrome
- Corian
- Formica
- Glass
- Linoleum
- Metal
- Non-Porous Plastic
- Glazed Porcelain
- Sealed Granite
- Sealed Marble
- Stainless Steel
- Vinyl
- Finished Wood
- Painted Wood

Medical Environments

USE SITES

- Ambulances
- Emergency Medical Transport Vehicles
- Anesthesia Rooms
- Anesthesia Areas
- Assisted Living Homes
- Full Care Nursing Homes
- CAT Laboratories
- Central Service Areas
- Central Supply [Rooms] [Areas]
- Critical Care Units
- CCUs
- Dialysis Clinics
- Emergency Rooms
- RS (Registered Sanitarian) Health Care Settings
- RS (Registered Sanitarian) Health Care Facilities

- Home Health Care Settings
- Hospitals
- Intensive Care Units
- ICUs
- Laboratories
- [Medical] [Physician's] [Doctor's] Offices
- Medical Clinics
- Medical Facilities
- [Newborn] [Neonatal] Nurseries
- [Nursing] [Nurses'] Stations
- Orthopedics
- Outpatient Clinics
- Patient Restrooms
- Patient Rooms
- Pediatric Examination Rooms
- Pediatric Examination Areas
- Pharmacies
- Physical Therapy Rooms
- Physical Therapy Areas
- Radiology Rooms
- Radiology Areas
- X-Ray
- Surgery Rooms
- Operating Rooms
- ORs

SURFACES {Applicable to materials listed under USE SURFACES}

- Bed Pans
- [Exam] [Examination] Tables
- External Surfaces of Medical Equipment
- External Surfaces of Ultrasound Transducers
- Gurneys
- Hard, Non-Porous Environmental [Hospital] [Medical] Surfaces
- Hospital Bed [Railings] [Linings] [Frames]
- Patient Bed [Railings] [Linings] [Frames]
- IV Poles
- Patient Chairs
- Plastic Mattress Covers
- Reception Counters
- Reception Desks
- Reception Areas
- Stretchers
- Wash Basins

Dental Environments

USE SITES

- [Dental] [Dentist's] Offices
- Dental Operatory rooms

SURFACES {Applicable to materials listed under USE SURFACES}

- Dental Countertops
- Dental Operatory Surfaces
- [Dentist] [Dental] Chairs
- Hard, Non-Porous Environmental Dental Surfaces
- Light Lens Covers
- Reception Counters
- Reception Desks
- Reception Areas

Veterinary Environments

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.

Spray HY-GEN on hard, non-porous surfaces. Treated surfaces must remain visibly wet for 5 minutes. Allow surfaces to air dry.

After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

USE SITES

- [Animal] [Pet] Grooming Facilities
- Kennels
- Animal Housing Facilities
- Animal Life Science Laboratories
- [Livestock] [Swine] [Poultry] Facilities
- Pet Areas
- Pet Shops
- Pet Stores
- Small Animal Facilities
- Veterinary Hospitals
- Animal Hospitals
- Veterinary Clinics
- Veterinary Facilities

- Veterinary Offices

SURFACES {Applicable to materials listed under USE SURFACES}

- Animal Equipment Automatic Feeders
- Cages
- External Surfaces of Veterinary Equipment
- Feed Racks
- Fountains
- Hard, Non-Porous Environmental Veterinary Surfaces
- Pens
- Reception [Counters] [Desks] [Areas] [Stalls]
- Troughs
- Veterinary Care Surfaces
- Watering Appliances

Miscellaneous / General Environments

USE SITES

- Airplanes
- Blood Banks
- Boats
- Bowling Alleys
- Chillers
- Churches
- Colleges
- Correctional Facilities
- Cruise Lines
- Day Care Centers
- Dormitories
- Factories
- Funeral Homes
- Grocery Stores
- Gymnasiums
- Gyms
- Health Club Facilities
- Hotels
- Industrial Facilities
- Laundromats
- Laundry Rooms Locker Rooms
- Manufacturing Facilities
- Manufacturing Plants
- Military Installations
- Motels
- Preschool Facilities

- Public Areas
- Recreational Centers
- Recreational Facilities
- Restroom[s] [Areas]
- School Buses
- Schools
- Shelters
- Shower Rooms
- Storage Rooms
- Storage Areas
- Supermarkets
- Trains
- Universities
- Wineries
- Yachts

SURFACES {Applicable to materials listed under USE SURFACES}

- Bathroom Fixtures
- Bath Tubs
- Behind and under Counters
- Behind and under Sinks
- Booster Chairs
- Cabinets Ceilings
- [Cellular] [Wireless] [Mobile] [Digital] Phones
- Chairs
- Computer Keyboards
- Computer Monitors
- Counters
- Countertops
- Cribs
- Desks
- [Diaper] [Infant] Changing Tables
- Diaper Pails
- Dictating Equipment Surfaces
- Doorknobs
- External toilet Surfaces
- External Urinal Surfaces
- Faucets
- Floors
- Garbage Cans
- Trash Cans
- Grocery Store Carts
- Supermarket Carts
- Hampers
- Hand Railings

- Headsets
- Highchairs
- Lamps
- Linoleum
- Playpens
- Shelves
- Showers
- Shower Stalls
- Sinks
- Stall Doors
- Tables
- Telephones
- Tiled Walls
- Toilet Rims
- Toilet Seats
- Towel Dispensers
- Toys
- Vanity Tops
- Vanities
- Other Telecommunications Equipment Surfaces

OPTIONAL GRAPHICS



SALTWATER BIOCIDES
SAFE SUSTAINABLE SANITATION

Hy•GEN



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store this product in its original sealed container at room temperature, away from direct sunlight and heat.

Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

{For Containers Less Than or Equal to 5 Gallons}

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

{For Containers Greater than 5 Gallons}

Container Handling: Refillable container. Refill this container with HY-GEN only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, thoroughly rinse the interior of the container with water, drain rinsate, following disposal instructions. Then offer for recycling if available or reconditioning if appropriate.